

the second stopper is moved to move the third stopper by compressing the first medicament component, thereby moving the first stopper for piercing with the piercing end by compressing the second medicament component; and

the first and second medicament components are mixed by moving the third stopper to an enlarged diameter portion of the lumen and moving second stopper to displace the first medicament to between the first and third stoppers.

22. (New) The method of claim 18, wherein the a cartridge that comprises the tube, needle, stoppers, and medicament, is fired by an injection device to inject the medicament.

**IN THE ABSTRACT:**

Please replace the Abstract with the one submitted herewith.

**REMARKS**

Claims 1-7, 9-13, and 15-22 presently appear in the present application for the Examiner's review and consideration. A copy of the marked up presently amended claims and a copy of the claims as presently pending are attached hereto for the Examiner's convenience. The claims appear properly renumbered to correspond with the office action numbering and with the sequence of previous claims.

In response to the election of species requirement, the election of species (C) is affirmed, to which Figs. 7-10 and original claims 1-13 and 15 are directed. Claim 14 has been cancelled without prejudice, and the right is reserved to file continuing applications to claim the subject matter thereof.

The language of the Abstract was objected to in the office action. Thus, attached is a substitute abstract, which corrects the format of the abstract.

Claims 8 and 10 were rejected under 35 U.S.C. § 112, second paragraph, as lacking antecedent basis for certain terms. Claim 8 was originally intended to be dependent on claim 7, but listed instead claim 1 as a base claim due to a typographical error, as evidenced by its content and the otherwise lack of antecedent basis. Claim 8 has been rewritten in independent form, and claim 10 has been amended to correct the typographical error in its listed base claim, providing the requisite antecedent basis, without enlarging or narrowing the claim scopes.

Claims 1-6 and 11-13 were rejected under 35 U.S.C. § 102(b) as anticipated by Reinhardt '333. Claim 1 is directed to a medicament cartridge for an injection system that includes needle and a medicament in a tube between first and second stoppers. The first stopper is disposed near a second end of the tube, and the second stopper is disposed near the first end of the tube. From this position of the first stopper, movement of the first stopper with respect to the tube towards a piercing end of the needle causes the piercing end to pierce the first stopper and open a fluid pathway for the medicament. This allows the ejecting of the medicament through the pathway by moving second stopper with respect to the tube toward the second end of the tube.

On the other hand, Reinhardt teaches a syringe for injecting two injection media. The syringe has two separate needles. One needle 15 is used first to inject media that is in compartment 6 disposed ahead of stopper 5. Stopper 5 is located in the middle of the tube, instead of being near one of the ends thereof as defined in claim 1. Needle 15 does not have any end that can pierce the stopper 5, nor is one necessary, as nothing in the syringe body closes off the chamber 6 from the needle.

Once this first medium is injected from the chamber 6, the stopper 5 is located all the way forward in the syringe body, and the needle 15 is replaced with a second needle 24. Needle 24 has a perforation part 23 that pierces stopper 5 to open compartment 7 and administer a second medium therefrom. The piercing occurs when the needle 24 is attached to the syringe body, and this does not involve any movement of the stopper 5 with respect to the body. This is opposed to the invention of claim 1, in which the cartridge is configured so that the piercing occurs when the first stopper moves with respect to the tube towards the needle. This provides the surprising and unexpected advantage over Reinhardt that the movement of the stoppers within the lumen, such as during the injection, can be used to open the medicament passage, without having to rely on the piercing occurring during the attachment of the needle. The opening of the passage can be made automatically, for instance, during the injection itself, both facilitating the process for the user and also promoting sterility as the passage is closed until the first stopper is moved within the tube and the needle does not require extra handling. Once the Reinhardt needle pierces the stopper, the passage is open, and the assembly must be cared for as an open syringe, providing less protection to the medium's sterility. Reinhardt also relies on the user to switch needles and essentially open the second chamber by hand, by inserting the second needle, requiring more

complex operation and diminishing the protection of the sterility of the assembly. Thus, claim 1 is neither anticipated nor obvious over Reinhardt.

Claim 2 specifically recites the structure as configured such that the movement of the second stopper causes the first stopper to move and be pierced, which enables, for example, the same injection motion of the second stopper to open the passageway. On the other hand, in the Reinhardt disclosure, the second needle is not taught to be in a position to pierce the stopper until the stopper to be pierced can no longer move. Claim 2 is thus patentably distinct from Reinhardt on its own merits.

Claim 13 defines the cartridge as configured for use in combination with an injection device for firing the cartridge to expel the medicament. This is neither taught nor suggested in Reinhardt, which shows the chambers containing the media as directly part of an integral hand-operated syringe, which is not configured for firing by any other device. Similarly, claim 16, positively recites an injection device. This is particularly advantageous in an injector, such as a jet injection device, or a powered mini-needle injection device, in which the cartridge can be loaded and opened during or just before firing the device.

Claims 7 and 8 were rejected under 35 U.S.C. § 103(a) over Reinhardt in view of van der Wal '286. Van der Wal does not remedy the shortcomings of Reinhardt discussed above, as no portion of the needle pierces any stopper.

The office action includes the contention that in view of Reinhardt it would have been obvious to combine the Reinhardt teaching with the teaching of mixing two components of van der Wal. Reinhardt, however, teaches away from making such a combination, as it specifically states that the media in the two compartments 6 and 7 "are not to be injected at the same part of the body nor at the same time." (Col. 3, lines 14-16.) Thus, one of ordinary skill in the art not only would have lacked any incentive to modify Reinhardt to mix the two media, but is specifically taught away from doing so by Reinhardt. Moreover, Reinhardt goes to great pains to ensure that the two media do not mix and can be injected separately. For instance, two needles are provided with the syringe, and the first one must be replaced by the second one to inject the second medium. Further, as no needle changing is needed in van der Wal, there is no motivation or suggestion to use the second needle of Reinhardt to reach a previously sealed medium compartment. Claims 7 and 8 are thus patentably distinct from the references of record.


New claim 18 defines a method involving moving a first stopper within a lumen to be pierced by a needle, and moving a second stopper within the lumen to eject the

medicament therefrom. This is not taught or suggested in the references, as the stopper in Reinhardt is not moved within the syringe body when pierced by the needle. Claim 18 is consequently also patentably distinct from the references, and the remaining new claims are also believed to be patentable on their own merits.

No fee is believed to be due for the present amendment. Please charge any required fees, however, to Winston & Strawn Deposit Account No. 501-814.

Respectfully submitted,

Nov. 22, 2002  
Date

  
\_\_\_\_\_  
E. Bradley Gould (Reg. No. 41,792)  
For: Allan A. Fanucci (Reg. No. 30,256)

**WINSTON & STRAWN**  
Customer No. 28765

202-371-5771

## AMENDED CLAIMS

1. (Amended) A medicament cartridge for an injection system comprising:

- a medicament;
- a tube having first and second ends and a lumen with a longitudinal axis for retaining the medicament therein;
- a needle operatively associated with the second end of the tube and having a piercing end extending into the lumen;
- a first stopper within the lumen located at a first position near the second end moveable within the lumen along the longitudinal axis; and
- a second stopper within the lumen located at a second position near the first end moveable within the lumen along the longitudinal axis,

wherein[, relative] movement [between] of the first stopper [and] with respect to the tube from the first position toward the needle causes the piercing end of the needle to pierce the first stopper to create a fluid pathway for the medicament through the needle, and movement of the second stopper with respect to the tube from the second position toward the second end of the tube compresses the medicament held between the second stopper and the first stopper so that the medicament is expelled through the fluid pathway.

8. (Amended) The cartridge of claim [6] 7, wherein a first medicament component is present between the second and third stoppers, and a second medicament component is present between the third and first stoppers, such that, movement of the third stopper to the enlarged diameter portion allows the first and second medicament components to mix to form the medicament.

10. (Amended) The cartridge of claim [1] 9, wherein the second stopper has a medicament contacting surface configured and dimensioned to mate with the frustoconical shape of the first stopper to minimize volume of medicament remaining in the lumen after the injection is completed.

13. (Amended) The cartridge of claim 1, wherein the cartridge is [used] configured for use in combination with an injection device for firing the cartridge to expel the medicament.

## PRESENTLY PENDING CLAIMS

1. (Amended) A medicament cartridge for an injection system comprising:
  - a medicament;
  - a tube having first and second ends and a lumen with a longitudinal axis for retaining the medicament therein;
  - a needle operatively associated with the second end of the tube and having a piercing end extending into the lumen;
  - a first stopper within the lumen located at a first position near the second end moveable within the lumen along the longitudinal axis; and
  - a second stopper within the lumen located at a second position near the first end moveable within the lumen along the longitudinal axis,wherein movement of the first stopper with respect to the tube from the first position toward the needle causes the piercing end of the needle to pierce the first stopper to create a fluid pathway for the medicament through the needle, and movement of the second stopper with respect to the tube from the second position toward the second end of the tube compresses the medicament held between the second stopper and the first stopper so that the medicament is expelled through the fluid pathway.
2. The medicament cartridge of claim 1, wherein movement of the second stopper toward the second end of the tube compresses the medicament between the first stopper and the second stopper to move the first stopper toward the second end of the tube to allow the piercing end of the needle to pierce the first stopper and create the fluid pathway for the medicament through the needle.
3. The cartridge of claim 1, wherein the piercing end of the needle has a bevel.
4. The cartridge of claim 1, wherein the needle has an injecting tip extending beyond the second end of the tube.

5. The cartridge claim 1, wherein the injecting end of the needle has a bevel.

6. The cartridge of claim 1, wherein the tube is cylindrical.

7. The cartridge of claim 1, wherein the lumen has a portion with an enlarged diameter, and further comprising a third stopper within the lumen located between the second stopper and the enlarged diameter and moveable within the lumen along the longitudinal axis.

9. The cartridge of claim 1, wherein the first stopper has a frustroconical shape.

10. (Amended) The cartridge of claim 9, wherein the second stopper has a medicament contacting surface configured and dimensioned to mate with the frustroconical shape of the first stopper to minimize volume of medicament remaining in the lumen after the injection is completed.

11. The cartridge of claim 1, wherein the first stopper has a dimple and narrow cross-section where the needle penetrates the first stopper.

12. The cartridge of claim 1, wherein the lumen has a cylindrical shape.

13. (Amended) The cartridge of claim 1, wherein the cartridge is configured for use in combination with an injection device for firing the cartridge to expel the medicament.

1465184 5,139,490  
15. The cartridge of claim 1, wherein the medicament is a liquid pharmaceutical preparation containing insoluble particles.

16. (New) An injection assembly comprising:  
the cartridge of claim 1; and  
an injection device configured for firing the cartridge to expel the medicament.



look for thru  
IOS.

2,688,967  
inv 5,605,542.

17. (New) A medicament cartridge for an injection system comprising:  
a medicament comprising first and second medicament components;  
a tube having first and second ends and a lumen with a longitudinal axis for retaining the medicament therein, wherein the lumen has a portion with an enlarged diameter;  
a needle operatively associated with the second end of the tube and having a piercing end extending into the lumen;  
a first stopper within the lumen located near the second end moveable within the lumen along the longitudinal axis;  
a second stopper within the lumen located near the first end moveable within the lumen along the longitudinal axis; and  
third stopper within the lumen located between the second stopper and the enlarged diameter and moveable within the lumen along the longitudinal axis, wherein the first medicament component is disposed between the second and third stoppers, and the second medicament component is present between the third and first stoppers;  
wherein movement between the first stopper and the needle causes the piercing end of the needle to pierce the first stopper to create a fluid pathway for the medicament through the needle and movement of the second stopper toward the second end of the tube compresses the medicament held between the second stopper and the first stopper so that the medicament is expelled through the fluid pathway;  
wherein movement of the third stopper to the enlarged diameter portion allows the first and second medicament components to mix to form the medicament.

and 4 medicament  
size (wherein  
mixed)  
w/ insoluble  
particles  
filter is needed

18. (New) A method of injecting a medicament, comprising:  
providing a medicament within a lumen of a tube that has first and second ends and between first and second stoppers that are disposed near the second and first ends of the tube, respectively;

moving the first stopper within the lumen towards a needle that is associated with the second end to cause a piercing end of the needle to pierce the first stopper to create a fluid pathway for the medicament through the needle; and

moving the second stopper within the lumen towards the second end to compress to compress the medicament to expel the medicament through the fluid pathway.

19. (New) The method of claim 18, wherein movement of the second stopper toward the second end of the tube compresses the medicament between the first stopper and the second stopper to move the first stopper toward the second end of the tube for piercing the first stopper with the piercing end of the needle and create the fluid pathway for the medicament through the needle.

20. (New) The method of claim 18, wherein the medicament is expelled through an injecting tip of the needle that extends beyond the second end of the tube.

21. (New) The method of claim 18, wherein:  
a first medicament component of the medicament is provided between the second and a third stopper in the lumen;  
a second medicament component is provided between the third and first stoppers in the lumen;  
the second stopper is moved to move the third stopper by compressing the first medicament component, thereby moving the first stopper for piercing with the piercing end by compressing the second medicament component; and  
the first and second medicament components are mixed by moving the third stopper to an enlarged diameter portion of the lumen and moving second stopper to displace the first medicament to between the first and third stoppers.

22. (New) The method of claim 18, wherein the a cartridge that comprises the tube, needle, stoppers, and medicament, is fired by an injection device to inject the medicament.